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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/891,526 | 06/27/2001 | Martin G. Crosby | UROMED-1 | 3190 |
| 23599 | 7590 | 10/21/2003 | EXAMINER | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | PATTEN, PATRICIA A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/891,526

Applicant(s)

CROSBY ET AL.

Examiner

Patricia A Patten

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please see 'Addendum to Advisory' attached hereto.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-3, 5, 13-20 and 25-34.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The term 'effective amount of forskolin' in claim 35 was not previously considered and would require a new search and consideration. Further, this term may raise a New Matter issue.

ADDENDUM TO ADVISORY

The After Final amendment filed 9/22/03 will not be entered.

The Declaration submitted under 37 CFR 1.132 has been entered and considered.

The After final amendment as well as the Declaration fail to place the claims in condition for allowance for the following reason:

Claims 16-18 and 31-33 stand rejected under 35 USC 112 First paragraph for being enabled for the composition which was shown in Example 2 as indicated in the previous Office Actions. Applicant asserts in the Declaration that the reference Ferguson et al. is evidence to conclude that the composition of claim 35 will indeed work commensurate in scope with the claims. However, the composition as described in Ferguson et al. employs evening primrose oil. Although Applicant states that primrose oil is simply a source of GLA, as is borage seed oil, primrose oil none-the-less contains many inherent phytochemicals besides GLA which may have an effect when administered to a patient. It is noted that it is not absolutely clear that the composition according to Example 2 contained primrose oil because the Example states that this ingredient is optional, and was only used in some cases. Because this reference does not clearly indicate that the composition of claim 35 will work absent the presence of the

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primrose oil and/or vinpocetine, it is the opinion of the Examiner that the evidence set forth in the Declaration, as well as the Ferguson et al. reference is insufficient to overcome the outstanding rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Patricia A Patten
Examiner
Art Unit 1654

10/16/03



PATRICIA PATTEN
PATENT EXAMINER